

Atty Dkt No. OPF 10.02  
USSN: 09/462,218  
PATENT

ACCOMPANYING DOCUMENTS

Accompanying this Amendment are the following documents: (a) Substitute Figure Sheets 1/7 and 6/7; (b) a Petition for Extension of Time to respond to the Office Action; and (c) copies of the Change of Correspondence Address submitted 28 January 2002 and the confirmatory postcard showing receipt at the USPTO on 20 February 2002.

AMENDMENT

In the Figures:

Please substitute Figure Sheet 1/7 (Figure 1) with the attached Substitute Figure Sheet 1/7.

Please substitute Figure Sheet 6/7 (Figures 16 and 17) with the attached Substitute Figure Sheet 6/7.

REMARKS

Introductory Comments:

Claims 1-25 are pending in the application. Applicants note with appreciation that the Office has acknowledged applicants' election of Species VI, as provided for in the Response filed 14 March 2002. Claims 6-7, 9-12, 15-18, 20 and 23-25 have been

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withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b) as drawn to a non-elected species.

Accordingly, claims 1-5, 8, 13-14, 19, and 21-22 are currently under consideration and were examined in the Office Action dated 31 May 2002. Applicants note with appreciation that claim 22 has been indicated as allowable if rewritten in independent form to include base limitations. However, the Office has entered the following grounds of objection/rejection: (a) the drawings are objected to under 37 C.F.R. 1.84(p)(4); (b) claims 3 and 4 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite; (c) claims 1-5, 8, 13-14, 19 and 21 stand rejected under 35 U.S.C. §102(b) as unpatentable over U.S. Patent No. 5,125,892 to Drudik ("Drudik"); and (d) claim 22 is objected to as dependent upon a rejected base claim. Applicants respectfully traverse the objections/rejections for the following reasons.

Matters of Form:

Applicants respectfully direct the Office's attention to the Change of Correspondence Address form submitted in the instant case on 28 January 2002. As can be seen, all communications in this application should be sent to the following address:

POWDERJECT PHARMACEUTICALS PLC  
Florey House, The Oxford Science Park  
Oxford OX4 4GA  
United Kingdom  
Telephone: +44 1865 332 600  
Fax: +44 1865 332 601

A copy of this Change of Correspondence Address form and a copy of the confirmatory postcard showing receipt of the same by the USPTO have been attached

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hereto for the Office's convenience. Applicants again request that all future correspondence is directed to this new address.

Overview of the Amendment:

Figure 1 (Substitute Figure Sheet 1/7) has been corrected so that the tag line for element 33 indicates the replaceable capsule as a whole instead of indicating the plug (element 34) that forms a part of the capsule as originally shown. The correction is submitted to rectify an obvious error. Support for the correction to Figure 1 can be found in the specification at page 16, lines 12-29, and in Figure 2. The corrected drawing has been submitted in clean form and in "marked-up" form showing the change to the tag line.

Figure 16 (Substitute Figure Sheet 6/7) has been corrected so that the plug is correctly labeled by reference character 79 instead of "29" as originally shown. The correction is submitted to rectify an obvious error. Support for the correction to Figure 16 can be found in the specification at page 22, lines 18-37. The corrected drawing has been submitted in clean form and in "marked-up" form showing the change to the reference character.

No new matter has been added by way of the corrections to Figures 1 and 16, and the entry of Substitute Figure Sheets 1/7 and 6/7 is respectfully requested.

The Objection to the Figures:

The drawings were objected to under 37 C.F.R. §1.84(p)(4) on the basis that reference characters 33 and 34 were both used to designate a replaceable capsule. Correction was required.

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In response, applicants draw the Office's attention to the correction to Figure 1 wherein this error has been corrected. Reconsideration and withdrawal of the objection to the drawings is thus respectfully requested.

The Rejection under 35 U.S.C. §112, second paragraph:

Claims 3 and 4 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite. In particular, the Office has asked for clarification on the following claim phrase "wherein the plug and housing contact each other at upper and lower opposing faces thereof." The Office has requested reference numerals and clarification on the various elements recited in the subject phrase.

In response, applicants direct the Office's attention to Figures 1-3 and to the specification at page 16, lines 12-37. At line 19, the subject text reads "the capsule comprises two members, a stationary plug or core 34 and a sliding outer housing or sleeve 35" and at line 27 "the housing 35 has larger and smaller diameter cylindrical surfaces, 38 and 39, respectively, which surfaces initially confront, as a slight interference fit, complementary cylindrical surfaces of the plug 34." Thus, the claim phrase that the Office has objected to could be rewritten as —wherein the plug 34 and housing 35 contact each other at upper and lower opposing faces thereof, 38 and 39, respectively—.

With respect to applicants obligations under Section 112, applicants refer to the M.P.E.P., particularly Section 2173.02 entitled "*Clarity and Precision*," where it is stated that "the essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity." The Section goes on to direct that this clarity and particularity "must be analyzed, not in a vacuum, but in light of (1) the content of the disclosure provided by the specification; (2) the teachings of the prior art; and (3) the claim interpretation that

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would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Applicants submit that once the specification (and accompanying figures) is contemplated for what it teaches the ordinarily skilled artisan, it is clear that applicants have met their obligation for clarity and precision under Section 112, second paragraph. Reconsideration and withdrawal of the rejection of claims 3 and 4 under 35 U.S.C. §112, second paragraph, is thus respectfully requested.

The Rejection Under 35 U.S.C. §102(b):

Claims 1-5, 8, 13-14, 19 and 21 stand rejected under 35 U.S.C. §102(b) as unpatentable over Drudik. In particular, the Office asserts "Drudik discloses a capsule adapted for containing a dose of a therapeutic agent to be delivered within a pressurized fluid flow ... having a first member and a second member (14), wherein said first and second members are coupled together to provide a closed pocket (figs. 1 and 8-12) and one of said first and second members is moveable relative to the other member when a portion of said capsule is contacted with a pressurized fluid flow ... such that upon said relative movement a passage is formed through said capsule and said pocket is opened to expose the dose." Office Action at page 3. Applicants respectfully traverse for the following reasons.

Anticipation of a claim under §102 requires that each and every element of the claims be inherent in, or disclosed expressly by the anticipating reference. *Constant v. Advanced Micro-Devices, Inc.*, 7 USPQ2d 1057, 1064 (Fed. Cir. 1988). Exclusion of a single claimed element from a prior art reference is enough to negate anticipation by that reference. *Atlas Powder Co. v E.I. du Pont De Nemours & Co.* 224 USPQ 409, 411 (Fed. Cir. 1984). Further, anticipation basically requires identity with the prior art document (*Tyler Refrigeration v. Kysor Indus. Corp.*, 227 USPQ

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845 (Fed. Cir. 1985)), where the identical invention must be shown in as complete detail as is contained in the rejected claim (*Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989)). Finally, in order to anticipate, a prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public. *Akzo N.V. v. United States ITC*, 1 USPQ2d 1241 (Fed. Cir. 1986).

Drudik fails to anticipate applicants' recited devices since it does not disclose each and every element thereof. In particular, applicants' claim 1 recites a capsule "comprising a first member and a second member, wherein said first and second members are coupled together to provide a closed pocket for containing the dose" (emphasis added). Claims 2-5, 8 and 13 each depend either directly or indirectly from claim 1 and thus contain this same limitation, that is, (a) the first and second members establish a closed pocket, and (b) the pocket contains the dose of therapeutic agent. Applicants' claim 14 likewise recites an intermediate portion comprising "first and second members which are coupled together to provide a closed pocket for containing the dose of the therapeutic agent" (emphasis added). Claims 19 and 21 each depend directly from claim 14 and thus contain this same limitation, that is, (a) the first and second members establish a closed pocket, and (b) the pocket contains the dose of therapeutic agent.

The Office has equated Drudik's stopper (element 14) with this expressly recited feature of applicants' devices. However, Drudik's stopper does not form a closed pocket (see open aperture 35 in Figure 1). In addition, Drudik contains its dose of liquid medicament upstream of the stopper (the medicament is contained upstream of the stopper in compartment 28, see Figure 1 and the disclosure of Drudik at column 8, lines 23-58). Accordingly, Drudik cannot anticipate applicants' claims since it does not contain each and every element as required by applicants' claims.

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For all of the foregoing reasons, then, the rejection of claims 1-5, 8, 13-14, 19 and 21 under 35 U.S.C. §102(b) is improper. Reconsideration and withdrawal of the rejection is thus earnestly solicited.

The Objection to Claim 22:

Claim 22 was objected to on the basis that it depends from a rejected base claim, but was indicated as allowable if rewritten to contain all of the base limitations. However, as established above, the base claim rejection is improper. Accordingly, applicants submit that claim 22 is now in allowable form. Reconsideration and withdrawal of the objection to claim 22 is respectfully requested.

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CONCLUSION

Applicants respectfully submit that the claims as now pending define an invention which complies with the requirements of 35 U.S.C. § 112 and which is novel and nonobvious over the art. Accordingly, allowance is believed to be in order and an early notification to that effect is earnestly solicited.

If the Examiner notes any further matters which he believes could be expedited by a telephone call, he is requested to contact the undersigned in the UK at +44 1865 332 600.

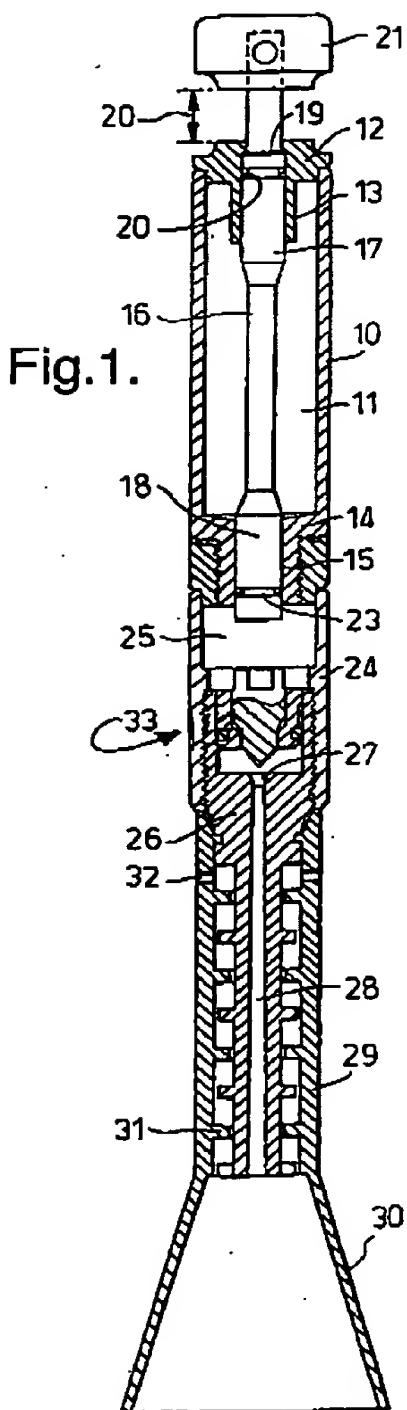
Respectfully submitted,

By:   
Thomas P. McCracken  
Registration No. 38,548

Date: 2 December 2002

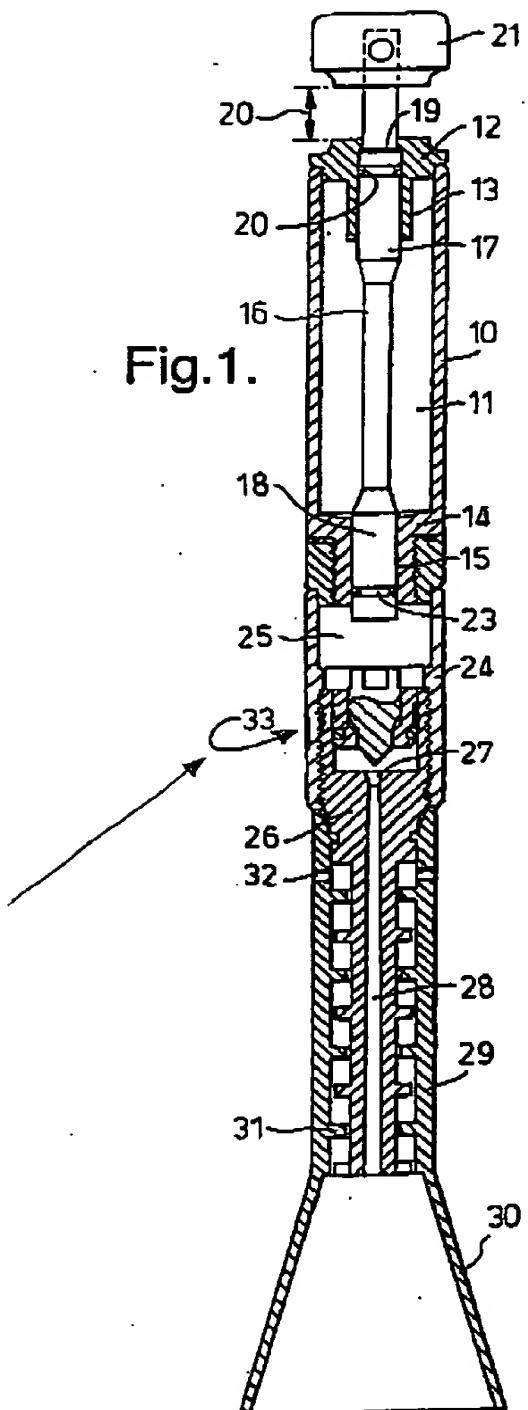
POWDERJECT PHARMACEUTICALS PLC  
Florey House, The Oxford Science Park  
Oxford OX4 4GA  
United Kingdom  
Telephone: +44 1865 332 600  
Fax: +44 1865 332 601

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SUBSTITUTED DRAWING

Fig.1.



\*( MARKED-UP VERSION)  
SUBSTITUTED DRAWING

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Fig.16.

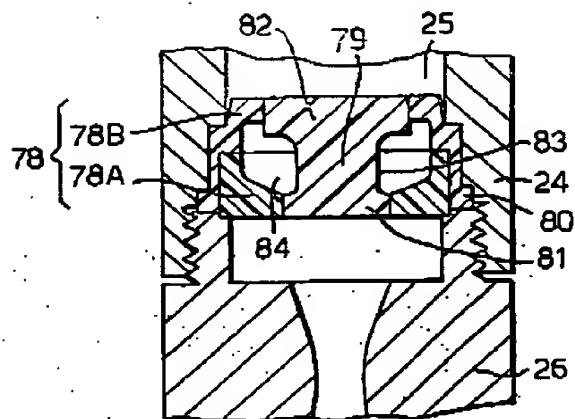
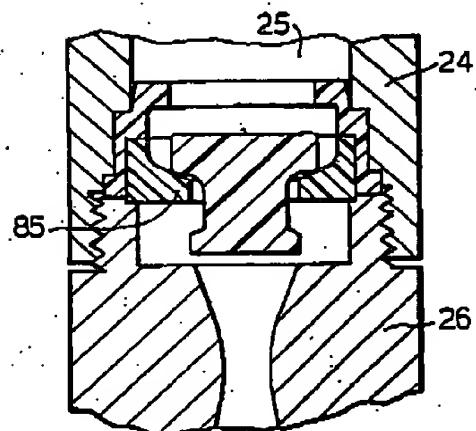


Fig.17.



SUBSTITUTED DRAWING

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Fig.16.

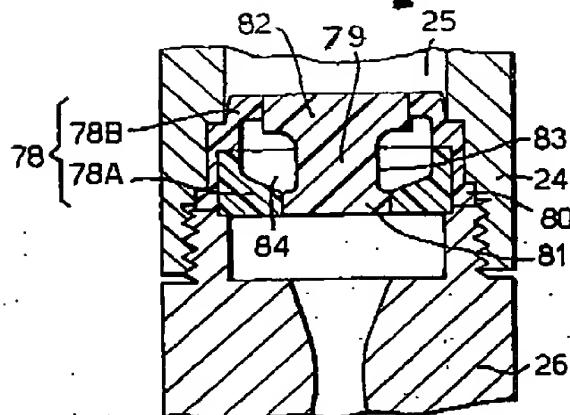
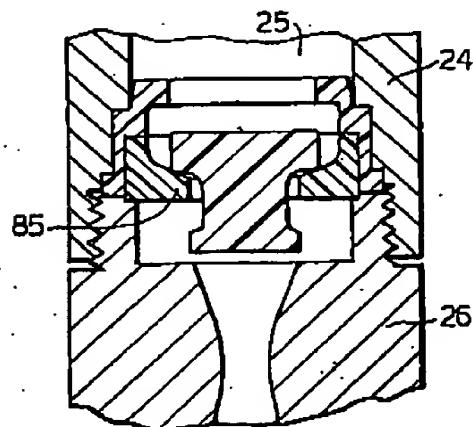


Fig.17.



\* (MARKED-UP VERSION)  
SUBSTITUTED DRAWING

OPF 10-02

ATTORNEY DOCKET: OPF 10.02      DATE: January 28, 2002  
Via First Class Mail

PAPER: Change of Correspondence Address (Application)

INVENTOR: POTTER

APPLICATION NO: 09/462,218

FILING DATE: 4 JANUARY 2000

*RECEIVED BY THE UNITED STATES PATENT AND TRADEMARK OFFICE*

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